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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,188

02/12/2004

Peter James Jenkins

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3089

22852

7590

08/21/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

08/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/776,188

Applicant(s)

JENKINS ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-24, 26-29 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-24, 26-29 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 29, 2007 has been entered.

Claims 8, 11-24, 26-29 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diabetes with Gibberellin A3 and Gibberellin A3 and A4/A7 mixture, does not reasonably provide enablement for the treatment of diabetes with Gibberellins of Formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The nature of the invention.

Drug discovery is one of the most labor intensive and expensive types of inventions; it can cost over \$500 million to bring a single new drug to market.

(B) The state of the prior art.

The art is unaware of successful treatment of diabetes with chemically analogous compounds.

(C) The predictability or lack thereof in the art.

"In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims" (see MPEP 2164.03). In the present case, the specification presents data showing the effect on blood glucose levels of Gibberellin A3. Based on the evidence of activity limited to Gibberellin A3, it cannot be predicted what other Gibberellins having diverse structural formulas encompassed by the present claims will have similar effect on blood glucose levels as Gibberellin A3.

(D) The amount of direction or guidance present.

The specification discloses a single specific compound and said compound with A4/A7 mixture which has a blood sugar lowering activity. However, this guidance is not commensurate with the full scope of the claims.

(E) Breadth of the claims.

The claims encompass an immense number of species having significant differences in structural formulas. For example, a compound of Formula (1) wherein R1, R2, R3, R4, R5, R6, R7, R8, R9, R10 and R11 are hydrogens is significantly different structurally from the compound of Formula (I) wherein R1, R2, R3, R5, R7, R8 and R10 are glycosylic ether groups, R4 is C20 alkyl, R6 and R10 are hydroxy groups.

(F) The quantity of experimentation needed.

Because there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Applicant's arguments filed June 29, 2007 have been fully considered but they are not persuasive.

Applicants contend that the claims have been amended to Gibberellin species comprising a C10-C19 lactone bridge which is in common with Gibberellin A3. This argument has not been found persuasive. Note that Reeve et al (J. of Experimental Botany, vol. 25, no. 89, pp. 431-45, 1974) disclose that activity of various gibberellins including those having a C10-C9 lactone bridge, varies and is unpredictable (page 436, Table 1). Further, the present claims still encompass, for example, various glycoside ethers. A person having ordinary skill in the art at the time the claimed invention was made would not have been able to predict how various glycoside ethers will affect the activity of the compounds encompassed by the present claims on their ability to treat diabetes.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boykin, Jr. (U.S. Patent No. 6,312,663) in combination with Wu et al (U.S. Patent No. 6,121,317).

The present claims encompass the treatment of complications and associated conditions of diabetes with a combination of gibberellins with anti-infective agents. Boykin, Jr. discloses that impaired wound healing is associated with diabetes. Wu et al disclose the treatment of wounds with a combination of gibberellins and antibiotics (column 2). Therefore, it would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to use a combination of gibberellins and anti-infective agents for the treatment of wounds which are the result from complication of diabetes.

Claims 11-15, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boykin, Jr. (U.S. Patent No. 6,312,663) in combination with Wu et al (U.S. Patent No. 6,121,317) and Lindenbaum (U.S. Patent 5,591,709).

The present claims encompass the treatment of complications and associated conditions of diabetes with a combination of gibberellins and insulin or growth factors. Boykin, Jr. teaches that impaired wound healing is associated with diabetes (column 1,

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lines 14-44). Wu et al disclose the use of gibberellins for wound healing. Lindenbaum disclose the use of insulin or growth factors for wound healing (column 2, lines 40-61 and column 3, lines 1-14). Therefore, a person having ordinary skill in the art at the time the claimed invention was made to combine gibberellins with insulin or growth factors and to use the resulting composition for treating wounds which are the results of complications from diabetes.

Claims 17-24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al (U.S. Patent No. 6,121,317) in combination with Lindenbaum (U.S. Patent No. 5,591,709).

Wu et al disclose gibberellins and their use for wound healing but do not disclose the use of gibberellins in combination with insulin or growth factors. Lindenbaum discloses the use of insulin and growth factors for wound healing (column 2, lines 40-62 and column 3, lines 1-14). Therefore, it would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to combine gibberellins with insulin or growth factors because such a person would have expected the resulting composition to be useful for wound healing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200